JUN 2 5 2001

K011424

Section 3
IL Test™ ProS - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
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Contact Person:

Carol Marble, Regulatory Affairs Manager
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Summary Prepared:

May 8, 2001

Name of the Device:

IL Test™ ProS

Classification Name(s):

864.7290	Factor Deficiency Tests	Class II
81GGP	Test, Qualitative and Quantitative Factor Deficiency	

Identification of Predicate Device(s):

K930327	IL Test™ Protein S

Description of the Device/Intended use(s):

IL Test™ ProS is a functional assay for the quantitative determination of free Protein S in human citrated plasma on IL coagulation systems as an aid in the diagnosis of hereditary and acquired Protein S deficiency.

This *in vitro* diagnostic test determines the functional activity of free Protein S by measuring the degree of prolongation of a prothrombin time in the presence of the tissue factor, phospholipids, calcium ions and activated Protein C. The Protein S activity is proportional to the prolongation of the clotting time of a Protein S deficient plasma to which the diluted sample was added.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

IL Test™ ProS is substantially equivalent to the predicate device (IL Test™ Protein S) in performance, intended use and safety and effectiveness.

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Summary of Performance Data:

Method Comparison

In method comparison studies evaluating 133 citrated plasma samples (49 normal donors and 84 patient samples) with Protein S levels range from 13% to 182% Protein S Activity on an ACL 3000, ACL Futura and Electra 1600C, the slopes and correlation coefficients (r) for IL Test™ ProS versus the predicate device are shown below:

New Device vs. Predicate Device

IL System	Slope	r
ACL 3000	1.01	0.982
ACL Futura	1.02	0.984
Electra 1600C*	1.01	0.986

***NOTE:** Only 131 plasma samples were tested on the Electra 1600C due to insufficient sample volume.

Within Run Precision

Within run precision assessed over multiple runs using two levels of control plasma gave the following results:

ACL 3000	**Normal Level**	**Protein S Deficient Level**
Mean (% Activity)	95	32.3
% CV	2.6	2.5

ACL Futura	**Normal Level**	**Protein S Deficient Level**
Mean (% Activity)	93.8	31.1
% CV	3.6	4.1

Electra 1600C	**Normal Level**	**Protein S Deficient Level**
Mean (% Activity)	90.9	27.2
% CV	1.4	2.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02421

Re: K011424
Trade Name: IL Test™ ProS
Regulation Number: 21 CFR § 864.7290
Regulatory Class: II
Product Code: GGP
Dated: May 8, 2001
Received: May 9, 2001

Dear Ms. Marble:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K011424

Device Name: IL Test™ ProS

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Josephine Bartolia

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K011424

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.019)